

Recommended references for the joint meeting of the

Pediatric Subcommittee
of the Anti-Infective Drugs Advisory Committee
and the
Pediatric Subcommittee of the Oncologic Drugs Advisory Committee

The development of new drugs for children with cancer has many challenges. Among them are the life threatening nature of the diseases, the relative rarity of pediatric cancer, the likelihood that each patient will probably take part in only one trial, and the specialized resources necessary to care for children with cancer. The following papers provide some background on the processes in current use, and what the results and expectations are.

Weitman S, Carlson L, Pratt CB New drug development for pediatric oncology.
Invest New Drugs 14(1): 1-10 1996
A perspective and overall summary with examples

Shah S, Weitman S, Langevin AM, Bernstein M, Furman W, Pratt C Phase I therapy trials in children with cancer. J Pediatr Hematol Oncol 20(5): 431-8 1998
Results and expectations with regard to safety and efficacy of Phase I studies

Smith M, Bernstein M, Bleyer WA, Borsi JD, Ho P, Lewis IJ, Pearson A, Pein F, Pratt C, Reaman G, Riccardi R, Seibel N, Trueworthy R, Ungerleider R, Vassal G, Vietti T Conduct of phase I trials in children with cancer. J Clin Oncol 16(3): 966-78 1998
An international consensus document on the design and implementation of Phase I studies

Weitman S, Ochoa S, Sullivan J, Shuster J, Winick N, Pratt C, Vietti T, Harris M Pediatric phase II cancer chemotherapy trials: a Pediatric Oncology Group study. J Pediatr Hematol Oncol 19(3):187-91 1997
A review of data and perspective on Phase II studies in oncology

In addition, we are including the following documents from FDA. All can be found on the FDA website.

February 11, 2000, "Pediatric Cancer Therapeutics: Letter of Interest"
<http://www.fda.gov/cder/pediatric/pedcancerletter.htm>

"Draft Guidance for Industry: Pediatric Oncology Studies in Response to a Written Request"
<http://www.fda.gov/cder/guidance/3756dft.htm>

"Sample of a Written Request for a Pediatric Oncology Drug Product Plan"
<http://www.fda.gov/cder/pediatric/oncologytemplate.htm>